

What is claimed is:

1. A crystalline Form I of Compound I having an X-ray powder diffraction pattern comprising the following 2 θ value measured using CuK α radiation: 6.3.
2. A crystalline Form I of Compound I having an X-ray powder diffraction pattern comprising the following 2 θ values measured using CuK α radiation: 6.3, 19.0 and 25.5.
3. A crystalline Form I of Compound I of Claim 2 diffraction pattern further comprising the following 2 θ values: 12.7, 22.0, 24.9 and 38.6.
4. A crystalline Form I of Compound I having an X-ray powder diffraction pattern substantially similar to that set forth in Figure 1a as measured using CuK α radiation.
5. A crystalline Form I of Compound I having differential scanning calorimetric curves substantially similar to those set forth in Figure 3.
6. A crystalline Form I of Compound I having differential scanning calorimetric curves comprising one endotherm at approximately 141°C and one endotherm at approximately 143°C, as measured at a ramp rate of 1°C/min.

7. A crystalline Form I of Compound I having a Fourier transform infrared pattern comprising at least one of the following infrared peaks: 3462, 3285, 3106, 2770, 2752, 1991, 1882, 1747, 1696, 656, 1651, 1332, 1253 and 557.
8. A crystalline Form I of Compound having a Raman peak pattern comprising at least one of the following peaks: 1739 and 1653, as measured using a spectrometer.
9. A pharmaceutical composition useful for treatment of a human disease comprising crystalline Form I of Compound I and a pharmaceutically acceptable carrier.
10. The composition of Claim 9, wherein a substantial percentage of Compound I is present as Form I.
11. The composition of Claim 9, wherein at least 99.9% of Compound I is present as Form I.
12. The composition of Claim 9, wherein at least 98% of Compound I is present as crystalline Form I.
13. The composition of Claim 9, wherein at least 95% of Compound I is present as crystalline Form I.
14. The composition of Claim 9, wherein at least 90% of Compound I is present as crystalline Form I.
15. The composition of Claim 9, wherein at least 85% of Compound I is present as crystalline Form I.

16. The composition of Claim 9, wherein at least 80% of Compound I is present as crystalline Form I.
- 5 17. The composition of Claim 9, wherein the disease is depression or anxiety.
- 10 18. A process for preparation of a pharmaceutical composition, comprising admixing Form I of Compound I with a pharmaceutically acceptable carrier.
- 15 19. The process of Claim 18, further comprising obtaining Form I of Compound I of substantial purity.
- 20 20. A method for treatment of a human disease, wherein the method comprises administering to a human subject suffering such disease a therapeutically effective amount of crystalline Form I of Compound I.
- 25 21. The method of Claim 20, wherein the disease is a CNS disorder.
22. The method of Claim 20, wherein the disease is anxiety or depression.
- 30 23. A process of preparing of crystalline Form I of Compound I, comprising stirring a slurry of Compound I in a solvent for a period of time of no less than one hour.

24. The process of Claim 23, wherein the solvent is selected from a group consisting of toluene, heptane, meta-xylene, ortho-xylene, para-xylene, isopropyl acetate, methanol, ethanol, 1-butanol, 1-octanol.
25. A crystalline Form III of Compound I having an X-ray powder diffraction pattern comprising at least one of the following 2θ values measured using $\text{CuK}\alpha$ radiation: 6.1 and 21.2.
26. A crystalline Form III of Compound I having an X-ray powder diffraction pattern comprising the following 2θ values measured using $\text{CuK}\alpha$ radiation: 6.1, 16.0, 21.2 and 25.7.
27. A crystalline Form III of Compound I of Claim 24 having an X-ray powder diffraction pattern further comprising the following 2θ values measured using $\text{CuK}\alpha$ radiation: 17.2, 20.3 and 26.5.
28. A crystalline Form III of Compound I of Claim 25 having an X-ray powder diffraction pattern further comprising the following 2θ values measured using $\text{CuK}\alpha$ radiation: 12.2, 15.5, 16.4, 17.2, 18.4, 19.3, 20.3, 21.6, 22.3, 23.1, 24.4, 25.0, 26. and 27.8.
29. A crystalline Form III of Compound I having an X-ray powder diffraction pattern substantially similar to that set forth in Figure 1c as measured using $\text{CuK}\alpha$ radiation.

- 5 30. A crystalline Form III of Compound I having a differential scanning calorimetric curve substantially similar to that set forth in Figure 5.
- 10 31. A crystalline Form III of Compound I having a differential scanning calorimetric curve comprising an endotherm at approximately 132°C, as measured at a ramp rate of 1°C/min.
- 15 32. A crystalline Form III of Compound I having a Fourier transform infrared pattern comprising at least one the following infrared peaks: 3450, 3297, 3058, 3101, 2810, 1982, 1972, 1930, 1888, 1820, 1742, 1691, 1663, 1336, 1288, 1250, 1196, 975, 873.
- 20 33. A crystalline Form III of Compound having a Raman peak pattern comprising at least one of the following peaks: 1734, 1662, 1333 and 1178, as measured using a spectrometer.
- 25 34. A pharmaceutical composition useful for treatment of a human disease comprising crystalline Form III of Compound I and a pharmaceutically acceptable carrier.
- 30 35. The composition of Claim 34, wherein a substantial percentage of Compound I is present as Form III.

36. The composition of Claim 34, wherein at least 99.9% of Compound I is present as Form III.
- 5 37. The composition of Claim 34, wherein at least 98% of Compound I is present as crystalline Form III.
38. The composition of Claim 34, wherein at least 95% of Compound I is present as crystalline Form III.
- 10 39. The composition of Claim 34, wherein at least 90% of Compound I is present as crystalline Form III.
40. The composition of Claim 34, wherein at least 85% of Compound I is present as crystalline Form III.
- 15 41. The composition of Claim 34, wherein at least 80% of Compound I is present as crystalline Form III.
42. The composition of Claim 34, wherein the disease is depression or anxiety.
- 20 43. A process for preparation of a pharmaceutical composition, comprising admixing Form III of Compound I with a pharmaceutically acceptable carrier.
- 25 44. The process of Claim 43, further comprising obtaining Form III of Compound I of substantial purity.
- 30 45. A method for treatment of a human disease, wherein the method comprises administering to a human subject suffering from such disease a

therapeutically effective amount of crystalline Form III of Compound I.

- 5 46. The method of Claim 45, wherein the disease is a CNS disorder.
47. The method of Claim 45, wherein the disease is anxiety or depression.
- 10 48. An Amorphous Form of Compound I having an X-ray powder diffraction pattern substantially similar to that set forth in Figure 1d as measured using CuK α radiation.
- 15 49. An Amorphous Form of Compound I having a differential scanning calorimetric curve substantially similar to that set forth in Figure 6.
- 20 50. An Amorphous Form of Compound I having differential scanning calorimetric curves substantially similar to those set forth in Figure 15.
- 25 51. An Amorphous Form of Compound I having differential scanning calorimetric curve comprising a glass transition temperature at approximately 30°C, as measured at a ramp rate of 1°C/min.
- 30 52. A pharmaceutical composition useful for treatment of a human disease comprising Amorphous Form of

Compound I and a pharmaceutically acceptable carrier.

- 5 53. The composition of Claim 52, wherein a substantial percentage of Compound I is present as Amorphous Form.
- 10 54. The composition of Claim 52, wherein at least 99.9% of Compound I is present as Amorphous Form.
55. The composition of Claim 52, wherein at least 98% of Compound I is present as Amorphous Form.
- 15 56. The composition of Claim 52, wherein at least 95% of Compound I is present as Amorphous Form.
57. The composition of Claim 52, wherein at least 90% of Compound I is present as Amorphous Form.
- 20 58. The composition of Claim 52, wherein at least 85% of Compound I is present as Amorphous Form.
59. The composition of Claim 52, wherein at least 80% of Compound I is present as Amorphous Form.
- 25 60. The composition of Claim 52, wherein the disease is depression or anxiety.
- 30 61. A process for preparation of a pharmaceutical composition, comprising admixing Amorphous Form of Compound I with a pharmaceutically acceptable carrier.

62. The process of Claim 61, further comprising obtaining Amorphous Form of Compound I of substantial purity.
- 5 63. A method for treatment of a human disease, wherein the method comprises administering to a human subject suffering from such disease a therapeutically effective amount of Amorphous Form of Compound I.
- 10 64. The method of Claim 63, wherein the disease is a CNS disorder.
- 15 65. The method of Claim 63, wherein disorder is anxiety or depression.
- 20 66. A pharmaceutical composition useful for treatment of a human disease comprising crystalline Form II of Compound I and a pharmaceutically acceptable carrier.
- 25 67. The composition of Claim 66, wherein a substantial percentage of Compound I is present as Form II.
- 30 68. The composition of Claim 66, wherein at least 99.9% of Compound I is present as Form II.
69. The composition of Claim 66, wherein at least 98% of Compound I is present as Form II.
70. The composition of Claim 66, wherein at least 95% of Compound I is present as Form II.

71. The composition of Claim 66, wherein at least 90% of Compound I is present as Form II.
- 5 72. The composition of Claim 66, wherein at least 85% of Compound I is present as Form II.
73. The composition of Claim 66, wherein at least 80% of Compound I is present as Form II.
- 10 74. The composition of Claim 66, wherein the disease is depression or anxiety.
- 15 75. A method for treatment of a human disease, wherein the method comprises administering to a human subject suffering from such disease a therapeutically effective amount of Form II of Compound I.
- 20 76. The method of Claim 75, wherein the disease is a CNS disorder.
77. The method of Claim 75, wherein the disorder is anxiety or depression.
- 25 78. A process for the preparation of 1-phenyl-3-[[3-(trifluoromethyl)phenyl]imino]-1H-indol-2-one (Compound I) which comprises reacting diphenylamine with oxalyl chloride and 3-(trifluoromethyl)aniline in a suitable solvent in one pot.
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79. A process for the preparation of 1-phenyl-3-[[3-(trifluoromethyl)phenyl]imino]-1H-indol-2-one (Compound I) which comprises reacting diphenylamine with oxalyl chloride and 3-(trifluoromethyl)aniline in a suitable solvent, and isolating the 1-phenyl-3-[[3-(trifluoromethyl)phenyl]imino]-1H-indol-2-one (Compound I) as Form I.
80. The process of Claim 78, wherein the reaction is run in a solvent selected from a group consisting of toluene, heptane, meta-xylene, ortho-xylene, para-xylene, isopropyl acetate, methanol, ethanol, 1-butanol, 1-octanol.
81. The process of claim 78, wherein the reaction is run at a temperature range 30°C - 150°C.
82. The process of Claim 78, wherein the reaction is heated for a period from 1 to 48 hours.
83. The process of Claim 78, further comprising combining diphenylamine with oxalyl chloride to produce 1-phenylisatin followed by adding 3-(trifluoromethyl)aniline.
84. The process of Claim 78 to 83, further comprising crystallizing and isolating Compound I.
85. The process of Claim 78, further comprising collecting solids after cooling to room temperature and stirring for 1 to 48 hours.

86. Form I of Compound I obtained in accordance with the process of Claim 78 to 83.
- 5 87. Form II of Compound I obtained in accordance with any of the process of Claims 78, 80, 81, 82 and 83.
- 10 88. Form III of Compound I obtained in accordance with any of the process of Claims 78, 80, 81, 82 and 83.
- 15 89. Amorphous Form of Compound I obtained in accordance with any of the process of Claims 78, 80, 81, 82 and 83.
- 20 90. The use of a polymorphic form of Compound I for the manufacture of a medicament for the treatment of a human disease.
- 25 91. The use of Claim 90, wherein the polymorphic form of Compound I is selected from a group consisting of Form I, Form II, Form III and Amorphous Form of Compound I.
92. The use of Claim 90, wherein the human disease is depression.
93. The use of Claim 90, wherein the human disease is anxiety.